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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/079,829	05/15/98	SNOW	A PROTEO.P07

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HM22/0901

EXAMINER

COE, S

ART UNIT	PAPER NUMBER
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1651

12

DATE MAILED:

09/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/079,829

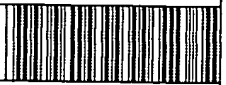
Applicant(s)

Snow et al.

Examiner

Susan Coe

Group Art Unit
1651



☒ Responsive to communication(s) filed on Jul 17, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-43 is/are pending in the application.

Of the above, claim(s) 14-43 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 10

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. Claims 1-43 are currently pending.

Election/Restriction

2. Applicant's election of Group I, claims 1-13, bark powder for species A, and oxindole alkaloids for species B in Paper No. 11, dated July 17, 2000 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 14-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected groups of invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.
4. Claims 1-13 are examined on the merits.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 5, 6, and 9 are rendered indefinite by the use of parentheses. The use of parentheses is considered indefinite because it cannot be determined when the enclosed limitation is or is not to be included in the claim. The use of the parentheses in the chemical names in claim 6 is acceptable.

6. Claim 9 is rendered indefinite by the phrase "various forms of malignancy." It is unclear what diseases or disorders are being referred to by this statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 9, 10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,039,949.

Applicant's claims are drawn to a composition comprising plant matter from a plant of genus *Uncaria*. The plant matter can be coupled with a pharmaceutically acceptable carrier.

US '949 teaches administering an extract from an *Uncaria* plant together with a pharmaceutical carrier (see claims 1, 7, and 8).

US '949 does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant; however, because the composition of US '949 is identical to the claimed composition, the composition of US '949 would inherently have the same effects on the human body as the claimed composition. Furthermore, these limitations appear in the preamble of applicant's claims. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The limitations in the preamble of the claim are considered to be a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the

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intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

8. Claims 1-10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 4,940,725.

The claims are drawn to a composition comprising plant matter from the plant *Uncaria tomentosa*. The extract is from the bark and contains oxindole alkaloids.

US '725 teaches an oral pharmaceutical product extracted from the root parts of *U. tomentosa*. The pharmaceutical extract contains oxindole alkaloids and is administered in a pharmaceutical carrier (see claims 1, 6, and 11). Extracting the "root parts" of *U. tomentosa* is considered to encompass using the bark of the root. US '725 teaches that the plant extract can be administered safely in a dosage up to 5 g/kg body weight (see column 17, lines 60-65).

US '725 does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant; however, because the pharmaceutical composition of US '725 is identical to the claimed composition, the composition of US '725 would inherently have the same effects on the human body as the claimed composition. Moreover, these limitations appear in the preamble of applicant's claims. As stated in the above 102(e) rejection, limitations in the preamble are not given patentable weight when they merely recite intended uses of a product fully described in the body of the claim.

9. Claims 1-6, 9, 10, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuppner et al. (Chromatographia (Dec, 1992) vol. 34, no. 11/12, pp. 597-600).

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Stuppner teaches that decoctions of *U. tomentosa* bark are used in South American folk medicine to treat a variety of disorders including arthritis and cancer. Extracts of the bark have also been used more recently to treat viral diseases and cancer. Stuppner reports that the bark extracts contain oxindole alkaloids.

Stuppner does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant; however, because the pharmaceutical composition described by Stuppner is identical to the claimed composition, the composition of Stuppner would inherently have the same effects on the human body as the claimed composition. Moreover, these limitations appear in the preamble of applicant's claims. As stated in the above 102(e) rejection, limitations in the preamble are not given patentable weight when they merely recite intended uses of a product fully described in the body of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,940,725.

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The claims are drawn to administering *U. tomentosa* in a composition that contains 70 to 95% plant extract by weight.

As stated above, US '725 anticipates administering an extract of *U. tomentosa*; however, US '725 does not teach administering a composition that contains 70 to 95% *U. tomentosa*. The amount of an active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been routine for an artisan of ordinary skill to determine the optimal amount of *U. tomentosa* to use in the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of *U. tomentosa* would have been obvious at the time of applicant's invention.

11. Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stuppner et al.

The claims are drawn to administering *U. tomentosa* in a composition that contains 70 to 95% plant extract by weight.

As stated above, Stuppner anticipates administering an extract of *U. tomentosa*; however, Stuppner does not teach administering a composition that contains 70 to 95% *U. tomentosa*. The amount of an active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It

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would have been routine for an artisan of ordinary skill to determine the optimal amount of *U. tomentosa* to use in the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of the amount of *U. tomentosa* would have been obvious at the time of applicant's invention.


12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 7:30 to 5:00 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
August 30, 2000



FRANCISCO PRATS
PRIMARY EXAMINER